REMARKS

In response to the final Official Action of August 31, 2010, no claims have been amended.

Claim Rejections - 35 USC §103

At pages 2-4, claims 1-4, 7-11, 15, 16, 19, 20, and 23-25 are rejected under 35 USC §103(a) as unpatentable over U.S. Patent 5,020,527, Dessertine, in view of WO 01/37909, Höerlins.

With respect to claim 1, the Office asserts that Dessertine discloses a dispenser for dispensing a substance in individual portions counted by a multi-use counter having a display incremented or decremented with the count portions dispensed and a dispense action detector for detection of the portion dispensing, with the dispenser comprising a body having a dispensing orifice, as well as a container for the substance, the container being integral with or accompanied on the body, a mechanism in the body and/or the container for dispensing individual portions of the substance to the orifice, the mechanism having a displaceable element for initiating the dispensing action, and an accommodation on the body for the counter with its detector arranged for detection of dispensing action of the mechanism. Reliance is placed on Figures 1 and 4 of Dessertine and associated elements set forth by the Office on pages 2-3 of the Action.

Höerlins is cited as disclosing a dispenser wherein the closure is adapted to co-operate with a portion of the body providing the accommodation for removably enclosing the counter in the accommodation, characterized in that the closure is tamper evident, with the assertion that it would be obvious to one of ordinary skill in the art at the time the invention was made to have modified the teaching of Dessertine to have included a closure cap adapted to enclose the counter to the body of the apparatus such that the removal of the closure cap would be tamper evident if removed from the dispenser as taught by Höerlins because enclosing the counter would prevent accidental activation of the counter and also alert a user if the closure is removed from the apparatus, and thus, the cap is tamper evident if removed. Applicant respectfully disagrees.

It is asserted that Höerlins teaches the presence of a tamper-evident closure because on removal of the dispenser's cap, a user would realize the closure has been removed. However, this interpretation does not take into account the fact that if the cap is removed, the counter can be replaced and the cap can be put back on without the user having any idea that the closure was

indeed tampered with. Any person having ordinary skill in the art would acknowledge that the proper interpretation of "tamper evident" takes this concept into account, and therefore, Höerlins does not disclose this feature of claim 1.

First, Applicant respectfully submits that the intended interpretation of "tamper-evident" in relation to the closure is consistent with the plain and ordinary meaning of these word; namely, to be immediately apparent to the user that the closure has been removed and replaced, and hence that the counter enclosed by the closure has been interfered with. Support for this meaning can be found in the article for the phrase "tamper-evident" on Wikipedia.org (http://en.wikipedia.org/wiki/Tamper-evident), enclosed as Attachment A. This article explains that the phrase "tamper-evident" describes a device that makes "unauthorized access to the protected object easily detected." Common techniques for making a device tamper-evident are seals and markings. A food jar, for example, commonly has a plastic wrap around the edge of its lid which is removed when the jar is opened such that the absence of the plastic wrap then indicates to a user that the jar has already been opened. Alternatively, packaging that tears open raggedly or otherwise cannot be resealed can be used to help indicate tampering. A tamper-evident device ensures that any interference to the enclosed product is immediately obvious to a user.

In a similar manner, the tamper-evident closure of this application describes a closure that has an arrangement which means that once it is removed and replaced, a user is immediately aware that the closure has been interfered (i.e. tampered) with. This is completely different to a closure that can be removed and replaced without trace of such activity, such as that described in Höerlins.

Advantageously, the use of a tamper-evident closure means that a user cannot accidentally fit the counter to a partially used or totally used dispenser without being aware that the counter will show an inaccurate number of doses. The tamper-evident closure which encloses the counter ensures that the user knows whether or not the closure has been removed, and hence whether or not the counter has been used before. Consequently, the risk that the user reads the counter and relies on an inaccurate number of doses indicated is greatly reduced.

Moreover, the tamper-evident closure prevents the user from unwittingly inserting a new counter, or replacing a counter, in the belief that the source in the dispenser is full.

Second, it is respectfully submitted that it is clear from the present application how the phrase "tamper-evident" should be interpreted. Page 4, lines 4-16 of the application as filed (WO 2005/056090) discloses a number of arrangements of the closure on the dispenser body so that it is tamper-evident. These tamper-evident arrangements of the closure are also exemplified in the figures. Figures 1-4, described on pages 9 and 10, show a closure (cap) 11 with a removable end disc 23. The central portion 32 of this end disc 23 is described at the bottom of page 9 as being "frangible with a tear groove 26" (see Figure 3). The specification at page 10, lines 8-25 states that once the dispenser is exhausted, the disc 23 is severed from the rest of the closure 11 and the counter is removed. The closure cannot therefore be resealed and it is evident to a user that the closure has been removed and replaced and hence that it has been tampered with.

Figures 5 and 6 show a closure (cap) 111 with an end disc 123, which is secured on the dispenser body by collar 121 having a tear groove 126 and a removable tear strip 151 around its edge. It is described at page 11, lines 15-22 of the application as filed that upon exhaustion of the source, the tear strip 151 is torn off allowing the counter to be removed. As stated above, the closure cannot be resealed and it is immediately evident to a user that the closure has been removed and replaced and hence that it has been tampered with.

Figures 7, 8 and 9 show a closure (plug) 351 with an end disc 356 that has an aperture 357 for viewing a counter 324. The counter is accommodated within a sleeve 358 of the plug that has a tear groove 359. Page 12, lines 13-18 of the application as filed describes that when the dispenser is exhausted, the aperture 357 is twisted against the resistance of the plug to tear the sleeve at its groove 359. The end disc and the counter can then be removed. The closure cannot be resealed and its removal and replacement (i.e. tampering) is evident to the user.

Therefore, it is clear from a reading of the specification, that "tamper evident" means that on removal of the closure it is immediately obvious to the user that the counter has already been used.

It is further respectfully submitted that neither Dessertine or Höerlins disclose or suggest a dispenser having a tamper-evident closure as required by the current claims.

Dessertine discloses a dispenser having a resettable counter and timer unit for monitoring the number of spray doses dispensed by an inhaler. The unit (21) shown in Figure 4 includes an automatic counter chip with a long-life miniature battery which is activated by downward movement of the container (15) against a lever (23) connected to the unit (21). The action of the lever on the unit simultaneously activates the timer which then signals a "beep" sixty seconds after the lever (23) has been depressed. Once a user has finished, the unit (21) may be simultaneously stopped and reset by depressing the reset button (29). As acknowledged by the Office in the Action, Dessertine does not disclose a closure adapted to enclose a counter and does not disclose a closure which is tamper-evident.

The Office relies on Höerlins to teach the presence of a closure which is adapted to cooperate with a portion of the body and enclose a counter, and to teach that the closure is tamper-evident. Specifically, the Office asserts that Höerlins discloses a tamper-evident closure because the cap (7) is removable and by seeing a removed cap the user would realize that the closure was tampered with. Applicant respectfully disagrees.

Höerlins discloses a counting mechanism (2) for counting the number of spray doses dispensed by an inhaler. The counting mechanism comprises a cap (7), a counting wheel (8) and a control wheel (9) and is mounted on the body of an inhaler as shown in Figure 1. The mounting of the counting mechanism on the inhaler is via an arrangement shown in Figures 2b and 6 and described at page 12 of the description. Essentially, the inhaler body is provided with flanges (40, 45) and the cap with an edge (13) and flanges (15) that co-operate therewith. Thus, the counting mechanism is fitted with the cap (7) tight over the flange of the coupling arrangement.

Höerlins does not, however, disclose a tamper-evident closure as required by the current claims. Rather, the cap (7) of Höerlins can be removed and replaced freely and repeatedly. As discussed above, the intended meaning of "tamper-evident" in the current application is that on removal of the closure it is immediately obvious to the user that the counter has already been used (i.e. that the closure has been tampered with). There is not, however, any feature of the cap (7) in Höerlins which would indicate to the user that the cap had been removed and hence that the counter had already been used. This is clear from the teaching at page 12, lines 10-13, which

states "the counting mechanism 2 is fitted with the cap 7 tight over the outer ring 41 of the coupling arrangement of the spray dose inhaler 1, and with the pin 14 on the cap edge 13 inserted into the recess 43 on the outer ring 41 of the coupling arrangement."

It is clear from this teaching that the cap (7) is held on the inhaler (1) by the engagement of the pin (14) on the cap's edge with a recess (43) on the inhaler body. Figure 2B shows the pin (14) and Figure 6 shows the recess (43). These two interlocking features are not, however, tamper-evident. Rather they cooperate in a key and lock type mechanism. Thus, the cap can be repeatedly removed and replaced.

The Office's submission that the cap (7) is tamper-evident if removed from the dispenser is an incorrect interpretation of the phrase "tamper-evident". Indeed there is no feature of either the pin (14) on the cap (7) or of the recess (43) which changes when the cap (7) is removed. Thus the cap (7) can be easily removed and replaced without any evidence thereof. Once the cap (7) is replaced on the inhaler body (1) it would not therefore be obvious to a user that it had in fact been removed. Hence, the counting mechanism of Höerlins comprising the cap (7) could easily be removed from a first dispenser and put onto a second partially used dispenser without any indication to the user that the closure had been tampered with. The user of the dispenser would therefore not know, or may forget, that the counter is inaccurate and therefore is at risk of not replacing the medicament source present in their dispenser at the appropriate time.

Absent any suggestion of the cap (7) comprising a tamper-evident feature, as is recited in claim 1, the present invention is not obvious to a person having ordinary skill in the art in view of Höerlins.

Because neither Dessertine nor Höerlins disclose or suggest the use of a tamper-evident closure, it is respectfully submitted that even if a person having ordinary skill in the art were to combine the teachings of Dessertine and Höerlins, it still would not arrive at the invention of the present application.

Furthermore, it is respectfully submitted that a person having ordinary skill in the art reading Höerlins would not be motivated to incorporate its cap into the device of Dessertine. There are key functional differences between the dispensers of Dessertine and Höerlins that would lead the skilled man away from combining their teachings.

Dessertine is directed to inhalers with a built-in counting means and timing means (49) (column 2, lines 41-42). Figure 4 of Dessertine, described at column 3, lines 40 *et seq.*, shows the details of the counting and timing unit (49). It has a curved back (51) for attachment to the inhaler by known plastic-to-plastic means or other known assembly means. The unit is also described as being detachable and usable with many inhalers adapted to have the unit removably attached thereto (column 3, lines 50-52).

In contrast and as discussed above, the counting mechanism of Höerlins is mounted on the inhaler by a coupling arrangement between the cap (7) and the inhaler shown in Figure 6. The cap (7) of Höerlins is therefore a functional part of the coupling arrangement of the counting mechanism to the inhaler. The counting mechanism relies on the cap (7) for it to be mounted on the dispenser body. This is completely distinct from the attachment of the unit in Dessertine. Thus, a person of ordinary skill in the art would not be able to incorporate the cap of Höerlins into the device of Dessertine without significantly modifying the attachment of Dessertine's counting and timing means.

Moreover, the counting means of Dessertine is reliant on an electronic counter activated by the downward movement of the canister against a lever which activates the automatic counter chip therein (Dessertine, column 3, lines 1-8). In contrast, the counting mechanism of Höerlins, shown in Figure 7, relies on a gearing mechanism and rotation of a control wheel (9) and a counting wheel (8). Thus, the counting mechanisms of these two documents are also completely different.

Furthermore the cap (7) in Höerlins is also a functional part of its counting mechanism. This is evidenced by the fact that it carries teeth on its interior (see Figure 2b). These teeth ensure that the counting wheel rotate by the correct amount and that the correct dose is displayed through the indicator window of the cap. The person of ordinary skill in the art reading Höerlins would therefore not be motivated to incorporate its cap into Dessertine, as it is not possible to incorporate the cap with teeth on its interior into its electronic counting mechanism. The teeth of the cap would serve no purpose in the electronic counting mechanism of Dessertine.

The person of ordinary skill in the art therefore has no motivation to combine the teachings of Dessertine with Höerlins. These two documents teach completely different

coupling arrangements between the counting means and the dispenser body, completely different counting mechanisms and the cap (7) is a functional part of both the coupling arrangement and the counting mechanism of Höerlins. Therefore, it would not have been obvious to a person of ordinary skill in the art to modify the device of Dessertine in order to incorporate the cap (7) taught in Höerlins.

Accordingly, applicant submits that the claims must be considered inventive over both Dessertine and Höerlins.

In summary, it is respectfully submitted that a person of ordinary skill in the art would not combine the cap 7 of Höerlins into Dessertine because the cap 7 cannot fulfill its functional role in the Dessertine device. Moreover, applicant submits that even if a person of ordinary skill in the art combines these teachings, he/she does not in any case arrive at the present invention as claimed since neither document teaches the presence of a tamper-evident enclosure. It is therefore submitted that the amended claims must be considered inventive.

It is therefore respectfully submitted that claim 1 is distinguished over Dessertine in view of Höerlins.

Dependent claims 3, 4, 7-11, 15, 16, 19, 20, and 23-25 are also believed to be distinguished over Dessertine in view of Höerlins at least in view of their ultimate dependency from amended claim 1.

Finally, dependent claims 32-34 should also be rejoined in view of the arguments in support of allowability of claim 1 from which these claims ultimately depend.

In view of the foregoing, it is respectfully submitted that the present application as amended is in condition for allowance and such action is earnestly solicited.

The undersigned respectfully submits that no fee is due for filing this Response. The Commissioner is hereby authorized to charge to deposit account 23-0442 any fee deficiency required to submit this paper.

Respectfully submitted,

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